REMARKS

Status of Claims

Claims 1-21, 23-38, and 61 are pending in the application. Claims 1-21, 23-32, 37-38, and 61 are rejected, and claims 33-36 are allowed. With this Amendment, claims 1, 37, 38, and 61 have been amended. No new matter has been added.

General Comments by the Examiner

According to the Examiner, "[b]efore applying art, the examiner notes that the positioning means of claims 1 and 61 fail the 3 part test for a means plus function clause, set forth in MPEP 2181 I, because it has structure capable of doing the function." As a result, "the examiner will not invoke 35 USC 112, sixth paragraph."

Rejection Under 35 U.S.C. § 102(b)

Claims 1-21, 23-29, and 38 are rejected under 35 U.S.C. § 102(b) as being anticipated by Rosenberg et al., U.S. Patent Number 4,538,618 ("Rosenberg").

In rejecting claims 1-29, 23-29, and 38, the Examiner stated that "Rosenberg has a blood flow sensor, i.e., fiber 16, located in a measuring head 2 and an indicator 36, for indicating the blood flow measurement" and that "[t]he device further includes a PCO2 sensor (see column 5, line 55)." It is the Examiner's position "that there would also be an indicator for indicating the PCO2 measurement, given that the reference provides an indicator for all of the other measured values." The Examiner goes on to state that in Rosenberg, "element 4 or element 26 both are devices that are capable of being used to hold the sensor in position adjacent a mucosal surface. As such, elements 4 and 26 are holder members. Both elements 4 and 26 have a passageway through which the blood flow sensor extends, so that it extends outside of the holder. The examiner notes that it is capable of meeting the use where the device is held at element 26 and the sensor 16 is positioned in contact with the digestive system of the patient. Hence, it meets

the claim language. Rosenberg meets the intended function of the positioning means and meets the claim limitation."

The Examiner further rejected independent claim 38 "for the reasons given above, noting that elements 26 and 4 are both at least partially flexible."

In response, independent claim 1 has been amended to recite "[a] device for assessing the degree of systemic perfusion in a patient, the device comprising: a blood-flow sensor . . . a PCO2 sensor . . . an indicating element operably connected to the blood-flow sensor and the PCO2 sensor to indicate the measured blood flow and the measured PCO2 . . . and a positioning element to locate and maintain the blood-flow sensor at a mucosal surface in the upper respiratory/digestive tract, the positioning element comprising a flexible holder member having a holder passage extending within at least a portion of the holder member and structured to receive the blood-flow sensor, wherein at least a portion of the blood-flow sensor is exposed along a longitudinal axis thereof and engages the mucosal surface in the upper respiratory/digestive tract."

To begin with, the Examiner states that Rosenberg discloses an indicator for indicating a blood flow measurement, and that in his opinion "there would also be an indicator for indicating the PCO2 measurement, given that the reference provides an indicator for all of the other measured values." However, such an indicator is not actually disclosed by Rosenberg. For this reason, Applicant respectfully suggests that the rejection of independent claims 1 and 38 under 35 U.S.C. § 102(b) is improper.

In addition, Rosenberg does not disclose a positioning element comprising a flexible holder member structured to receive a blood flow sensor as now recited in independent claim 1. Once again, in the rejection of independent claim 38 (which includes a limitation to "a flexible member having a sensor holder passage"), the Examiner stated that elements 26 and 4, which the Examiner equated to the claimed holder member, "are both at least partially flexible." Applicant respectfully disagrees with the Examiner's position regarding the flexibility of elements 26 and 4. According to Rosenberg, "an iron core 26 is secured to the portion of the optical fiber tail 22

disposed within the electrical coil 14 fixed in housing 4 so that the core is displaceable within the coil according to the displacement of the plunger 18 within the housing." (Col. 3, lines 13-18.) However, an "iron core" is not a flexible element, but rather a hardened, non-flexible element. Thus, Applicant respectfully disagrees with the Examiner's position that element 26 of Rosenberg is "at least partially flexible."

Furthermore, according to the disclosure in Rosenberg regarding use of the fluid flow detector, "the head 2 is gripped by the operator and is manipulated so as to apply pressure to the skin or other tissue being monitored. This pressure will cause plunger 8 to be displaced against the action of spring 12, so that the core 26 will in turn be displaced with respect to the coil 14 a distance corresponding to the pressure of application of the head against the subject's tissue." (Col. 3, lines 58-62.) If cylindrical housing 4 was flexible, it would not be possible to obtain an accurate displacement of iron core 26 relative to coil 14 because coil 14 is fixed within housing 4. In particular, a flexible housing would bend and deform when the head 2 is gripped by the operator and "manipulated so as to apply pressure to the skin or other tissue being monitored," thereby causing corresponding movement of coil 14 fixed within housing 4. As a result, the pressure reading derived from the displacement of iron core 26 would be skewed because as plunger 8 is moving iron core 26 relative to coil 14, coil 14 is also moving relative to iron core 26 as a result of the bending and flexing of the cylindrical housing. Therefore, in order to obtain an accurate pressure reading, housing 4 must be of a rigid construction so that the position of coil 14 remains fixed while iron core 26 is being displaced therein during use of the fluid flow detector. For this reason, Applicant respectfully disagrees with the Examiner's position that element 4 of Rosenberg is "at least partially flexible."

If the Examiner maintains his position regarding the flexibility of elements 4 and 26 in Rosenberg, Applicant respectfully requests that the Examiner point to the column and line number where such disclosure may be found.

Next, Rosenberg fails to disclose a flexible holder member structured to receive a blood-flow sensor, wherein at least a portion of the blood-flow sensor is exposed along a longitudinal axis thereof and engages the mucosal surface in the upper respiratory/digestive tract, as now

recited in independent claim 1. According to the teaching of Rosenberg, "[o]ptical fiber 16 includes an enlarged end 18 to be secured within plunger 8 by means of a fastener 20 passing through the plunger and engaging the head 18, such that the outer face of the enlarged end 18 is flush with the outer face of the plunger." (Col. 3, lines 5-9.) Rosenberg goes on to disclose that "laser 40 (FIG. 4) is energized so as to transmit a laser beam through one branch of the optical fiber 16, which beam is reflected back through another branch of the same optical fiber to the receiver unit 42, for measuring the blood flow through the tissue according to the Doppler effect." (Col. 3, line 65 to col. 4, line 3.) Thus, it is clear from the disclosure in Rosenberg that only an outer end face of the optical fiber 16 is exposed from the fluid flow detector and structured to contact the tissue surface being monitored. Dissimilarly, independent claim 1 requires a blood flow sensor that is exposed along a longitudinal axis thereof and engages the mucosal surface. Rosenberg does not disclose, teach, or suggest this configuration.

According to M.P.E.P. § 2143.01 V, "[i]f proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification." As a result, there is no suggestion or motivation to modify the structure of the Rosenberg device so that a portion of the fiber is exposed along a longitudinal axis thereof because the tissue contact surface in Rosenberg must continue to be the end surface of optical fiber 16 in order to obtain a blood flow measurement with the device. In particular, the end surface of optical fiber 16 both transmits a laser beam to the tissue and receives reflected laser light back from the tissue in order to measure blood flow via the Doppler effect. If the fluid flow detector in Rosenberg was modified such that optical fiber 16 was exposed along a longitudinal axis thereof, and optical fiber 16 engaged a tissue surface along this longitudinal axis instead of the end surface of the optical fiber, then the Rosenberg device would be unsatisfactory for its intended purpose. The Rosenberg device may be used to measure blood flow only if the end surface, and not an exposed longitudinal surface, is in contact with the tissue surface. Therefore, because Rosenberg fails to disclose, teach, or suggest each element of amended independent claim 1, and because there is no motivation for modifying the Rosenberg device to meet the structure recited in independent claim 1, Applicant respectfully requests that the rejection of claim 1 under 35 U.S.C. § 102 be withdrawn.

Claims 2-21 and 23-32 depend from independent claim 1. As such, these claims are allowable with their independent base claim. In addition, it is respectfully submitted that the combinations of features recited in claims 2-21 and 23-32 are patentable on their own merits, although this does not need to be specifically addressed herein since any claim depending from a patentable independent claim is also patentable.

Independent claim 38 has been amended to recite "[a] device for assessing the degree of systemic perfusion in a patient, the device comprising: a blood-flow sensor . . . an indicating element operably connected to the sensor to indicate the measured blood flow . . . and a sensor holder adapted to hold the blood-flow sensor adjacent a mucosal surface in the upper respiratory/digestive tract, the sensor holder comprising a flexible member having a sensor holder passage with the blood-flow sensor disposed therein, wherein at least a portion of the blood-flow sensor is exposed along a longitudinal axis thereof and engages the mucosal surface." Similar to the reasons stated above in reference to the rejection of independent claim 1, Rosenberg does not disclose, teach, or suggest a device for assessing the degree of systemic perfusion that includes a sensor holder having a flexible member with a sensor holder passage, wherein at least a portion of the blood-flow sensor is exposed along a longitudinal axis thereof and engages the mucosal surface, as now recited by claim 38. Furthermore, there is no motivation to modify the structure of the Rosenberg device to meet the structure recited in independent claim 38. Therefore, Applicant respectfully requests that the rejection of claim 38 under 35 U.S.C. § 102 also be withdrawn.

Rejection Under 35 U.S.C. § 103(a)

Claims 30, 37, and 61 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Rosenberg in view of Riccitelli et al., U.S. Patent No. 5,166,990 ("Riccitelli"). Claims 31 and 32 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Rosenberg in view of Boggett et al., WO 98/20794 ("Boggett").

In rejecting claims 30, 37, and 61 as being unpatentable over Rosenberg in view of Riccitelli, the Examiner states that Riccitelli "further teaches that it is known to monitor pH and

PCO2 in the same intravascular measuring device." Therefore, according to the Examiner, "it would have been obvious to modify Rosenberg to include a pH sensor, to provide a more complete picture of the patient's condition."

Independent claim 37 has been amended to recite "[a] device for assessing the degree of systemic perfusion in a patient, the device comprising: a blood-flow sensor . . . a pH sensor . . . an indicating element operably connected to the sensor to indicate the measured blood flow and the measured pH . . . and a flexible sensor holder having a holder passage extending within at least a portion of the sensor holder and structured to receive the blood-flow sensor, wherein at least a portion of the blood-flow sensor is exposed along a longitudinal axis thereof and engages the mucosal surface." Similarly, independent claim 61 has been amended to recite "[a] device for assessing the degree of systemic perfusion in a patient, the device comprising: a blood-flow sensor . . . a pH sensor . . . a PCO2 sensor . . . an indicating element operably connected to the blood-flow sensor, the pH sensor and the PCO2 sensor to indicate the measured blood flow, the measured pH and the measured PCO2 . . . and a positioning element for positioning the blood-flow sensor adjacent the mucosal surface, the positioning element comprising a flexible sensor holder having a holder passage extending within at least a portion of the sensor holder, wherein the blood-flow sensor is located within the holder passage, and wherein at least a portion of the blood-flow sensor is exposed along a longitudinal axis thereof and engages the mucosal surface."

As discussed in detail above in reference to the rejection of independent claims 1 and 38 under 35 U.S.C. § 102(b) as being anticipated by Rosenberg, Rosenberg does not disclose, teach, or suggest a device for assessing the degree of systemic perfusion in a patient that includes a flexible sensor holder having a holder passage, wherein at least a portion of the sensor is exposed along a longitudinal axis thereof and engages a mucosal surface. In addition, the combination of Rosenberg, Riccitelli, and Boggett does not disclose, teach, or suggest a device having the claimed structure. Furthermore, for at least the reasons stated above, there would be no motivation to modify the structure of the Rosenberg device to meet the structure recited in independent claims 37 and 61 because modifying the Rosenberg device in such a manner would render the device unsatisfactory for its intended purpose. Therefore, because Rosenberg,

Riccitelli, and Boggett fail to disclose, teach, or suggest each and every element of Applicant's invention as recited in claims 37 and 61, Applicant respectfully submits that the references do not render claims 37 and 61 obvious. As a result, Applicant respectfully requests that the rejection of independent claims 37 and 61 under 35 U.S.C. §103 be withdrawn.

Claims 30-32 depend from independent claim 1. As such, these claims are allowable with their independent base claim. In addition, it is respectfully submitted that the combinations of features recited in claims 30-32 are patentable on their own merits, although this does not need to be specifically addressed herein since any claim depending from a patentable independent claim is also patentable.

Allowed Claims

According to the Examiner, claims 33-36 are allowable "in that none of the art has the holder with an inner portion having a shape corresponding to the shape under the tongue, as claimed." Applicant respectfully acknowledges and thanks the Examiner for the indication of allowed claims.

Conclusion

Applicant respectfully submits that with the arguments and amendments presented herein all pending claims are allowable over the art of record, for at least the reasons discussed above, and respectfully requests that a Notice of Allowance with respect to all pending claims be issued in this case.

If the Examiner believes that a teleconference would be of further value in expediting the allowance of the pending claims, the undersigned can be reached at the telephone number listed below.

It is believed that no petition or payment for extension of fees is due. If, however, it is believed that any additional fees are necessary, the Commissioner is hereby authorized to charge or credit any such fees or overpayment to Deposit Account No. 50-1901 (Reference 11242-320).

Dated: 2/28/08

Respectfully submitted,

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